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Family Planning Digest

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Fundamental Research

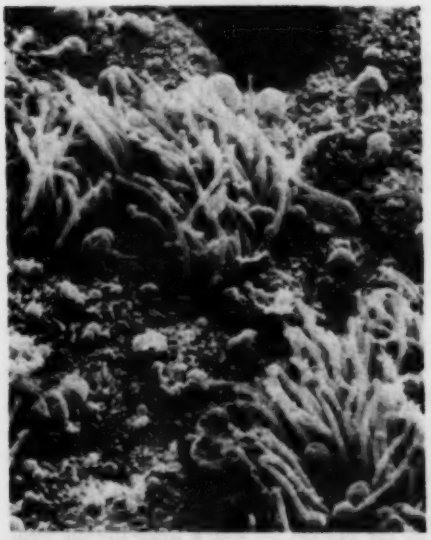
Research on Human Reproduction Provides New Leads to Male, Female Contraception

Unplanned pregnancies, whose number reach "epidemic proportions" annually in the United States and elsewhere, the resort to legal and illegal abortion by millions of women every year to terminate such unwanted conceptions, severe population pressures in many countries and the limitations of even the most effective methods of birth control (the pill and the IUD—used by some 60 million women the world over) lend special urgency to the search for new contraceptive methods, keynote speakers told 200 participants in a two-day symposium on Advances in Fertility Regulation Through Basic Research cosponsored by The Population Council and the Center for Population Research (CPR) of the National Institute of Child Health and Human Development. Observing that no new contraceptives have been developed since the pill was introduced in 1958 and the IUD reintroduced in the early 1960s, William A. Sadler, Chief of CPR's Population and Reproduction Grants Branch, stressed the critical importance of basic research by pointing out that:

> While there are many reasons for failure to produce new measures equal to these two or even a single one for the male, the major reason appears to be lack of scientific breakthroughs . . . rather than failure of application of existing knowledge to contraceptive development.

He noted that:

> Critical masses of relevant scientific information do not arise *de novo* but are created by accretions of knowledge obtained for the most part through basic research. Thus, basic research is the rate-limiting aspect of the development of the scientific breakthroughs that are clearly required for the introduction of new and significant measures for fertility regulation that will be accepted and used properly by diverse population groups.



Electron micrograph of surface of human uterus.

Among the most promising areas of fundamental research supported by CPR which might lead to new fertility control methods, Sadler said, are the hormonal, cellular and subcellular sites of essential processes relating to reproduction, with preference for pregnancy-specific and preimplantation processes. He excluded support of research relating to abortion because of "legislative, moral, ethical and religious objections to pregnancy termination." He also expressed reservations about "interception of spermatogenesis through use of spermicidal or other agents which act directly on germ cells" because of the possibly high risks of mutagenic or teratogenic effects.

Demonstrating the interrelationship of fundamental research and contraceptive development, M. C. Chang of the Worcester Foundation for Experimental Biology in Shrewsbury, Mass., who was a codeveloper of the oral contraceptive, pointed out that advances in the fields of endocrinology, steroidal chemistry and reproductive biology

laid the groundwork for the development of the pill, with the synthesis of the progestational compounds norethindrone and norethynodrel in 1951 playing a key role. Chang said interest in these compounds was originally related to aspects of fertility and not contraception, but that laboratory work on animals suggested their usefulness as a contraceptive agent and stimulated effort in that direction. Preliminary clinical investigations with these norsteroids demonstrated that they did indeed prevent pregnancy, but they also caused unacceptable breakthrough bleeding. Estrogen was added to reduce this bleeding; thus, the combination oral contraceptive was developed. He summed up:

> I am not sure whether [the] gynecologists... who suggested the hormonal treatment for contraception; [the] endocrinologists . . . who reported the effect of progesterone on ovulation and fertilization; or [the] chemists . . . who synthesized these compounds, were aiming to develop an oral contraceptive when they did their laboratory work. Most probably, they did their work . . . to satisfy their curiosity or for the enjoyment and the thrill of finding something new. . . .

He added:

> . . . it did not occur to me that I was making a discovery and my labor would be beneficial to 50 million women throughout the world 20 years later.

Elaborating on the necessity for continued fundamental research, Sheldon J. Segal, Director of The Population Council's Biomedical Division, pointed out that, although some 20 antifertility agents and devices for men and women are at various stages of development and testing, few are truly innovative and most are variants of existing methods. Of the leads now known to be feasible and being tested, he said:

> . . . it is possible that within a few years the contraceptive armamentarium will include an immunization method for women, a male pill supplemented by annual replacement of subdermal implants, an annual subdermal implant for women, an optimal IUD, bi-monthly or semi-annual injections for women or men, a monthly pill to be taken at the end of each month to bring on a menses irrespective of whether the cycle has been fertile, and, ultimately, if even this list of choices does not result in "near-perfect" contraception, a safe and effective chemical abortifacient.

However, he warned that none of these may ultimately succeed for reasons of safety, lack of adequate effectiveness or insurmountable problems of product engineering. Segal maintained that:

> The continuous identification of new leads is, perhaps, the critical part of the overall process of developing new contraceptives. The development of a flow of new ideas to serve as the basis for clinical trial depends heavily on studies fundamental to a greater understanding of the normal reproductive process. With this deeper understanding, potentially vulnerable points of interference can be more readily identified, and the basis established for empirical screening of compounds or natural products with potential anti-fertility action.

He observed that "the hopes for significant revolutionary breakthrough rather than incremental advances in contraception lie in the progress of basic research." Segal concluded:

> The reproductive process remains one of the least understood physiologic systems. . . . Several steps in the reproductive process which would appear most vulnerable to specific, controlled interference are still being probed by fundamental scientists for fuller understanding.

Research aimed at elucidating the mechanism of action, as well as the structures and functions of the enormously intricate hormonal system involved in the reproductive processes in both the female and the male, was reported at the symposium's scientific sessions. Since the various hormones are involved in such essential phenomena as the ovarian and menstrual cycles, the development and transport of ovum and sperm, the fertilizing capacity of the sperm, and the preparation of the uterus for implantation, an understanding of how their action is triggered, what cells in target organs are especially sensitive to them at various times, how they interact with such glands as the hypothalamus, the pituitary and the pineal is essential to the ultimate development of methods to interfere with their activity.

Research on the female reproductive system was reported from numerous centers around the country:

- Max Amos of the Neuroendocrinology Laboratory at the Salk Institute described efforts to apply to fertility control newly acquired knowledge of the Luteinizing Releasing Factor (LRF) that triggers release of gonadotropin from the pituitary. Three years ago, LRF was synthesized at the Institute and analogues developed, leading to its experimental use as a diagnostic and therapeutic tool to overcome long-standing amenorrhea. Theoretically, LRF could also be used to enhance the usefulness of the rhythm method, since it or an analogue might be administered so as to produce timed ovulation. Work is in progress to develop antagonists to LRF that would block its action and inhibit ovulation, thus preventing the possibility of pregnancy.
- Om Bahl of the Department of Biochemistry and Cell and Molecular Biology at the State University of New York (Buffalo) is working on the theory that it might be possible to regulate fertility by removal of circulating gonadotropins. It might be possible to do this by developing specific antibodies to these gonadotropins. The success of this approach would hinge on the specificity of the antibodies, since nonspecific activation of the body's immune responses could involve serious complications. The scientist has been studying the chemical structure of human chorionic gonadotropin (HCG) secreted by the placenta and involved in stimulating the production of progesterone, which helps maintain pregnancy. Study of the structure shows that about 90 percent of it is identical with other hormones, but about 10 percent of the amino acids of HCG are specific to it. Efforts to develop antigens to that 10 percent are in progress, and they should soon be ready for clinical testing. Another direction of interest has to do with the capacity of HCG to bind to the ovary and the possibility of interfering with the binding mechanism.

  It is known that specific receptors to various gonadotropins are present in both the male and female gonads, and work involving the ovarian receptors is being carried on in several laboratories.
- Bert O'Malley of the Baylor College of Medicine, in addition to extending what was previously known about the nature and function of the steroid receptors found in the various tissues of the organs of the reproductive system, is elucidating the major steps in the process by which progesterone stimulates uterine cells to produce substances

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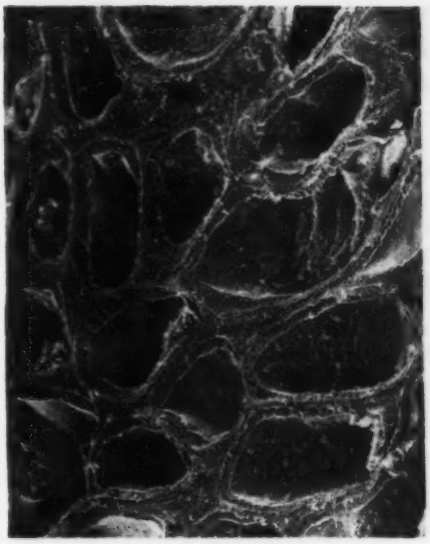
necessary for the maintenance of pregnancy. His research suggests the possible development of antiprogesterones that might block the binding of progesterone to uterine tissue or of chemical agents that would in some way disturb the receptor cycle.

● Maria Dufau of the Reproductive Research Branch of NICHD is trying to isolate, in purified form, the ovarian receptors for HCG. Once this is done, it might be possible to design new molecules to bind to these receptors, blocking the binding of HCG. If this could be accomplished, HCG's hormonal support of pregnancy could be blocked and a newly established pregnancy could be terminated.

Another area under investigation is the process of follicular development within the ovaries. Each ovary contains thousands of ova, each within a follicle, yet only one egg is released from an ovary each month. What causes scores of follicles and their contained ova to develop, but only one to mature fully and to be released? If this were known, it might be possible to interfere with the process and block ovum development.

● This is the problem addressed by A. Rees Midgley, Jr., of the University of Michigan Medical School. It is believed that two gonadotropins, luteinizing hormone (LH) and follicle-stimulating hormone (FSH), released by the pituitary gland and reaching the ovaries by means of the blood stream, interact in some way to cause follicular maturation. On the basis of recent data, Midgley and his colleagues suggest that estrogen secreted in the ovary at the beginning of the menstrual cycle stimulates development of the follicle and induces the synthesis of FSH receptors by the follicle. The FSH receptors bind some of the circulating FSH which, in turn, stimulates the follicle to secrete more estrogen. This process is thought to be responsible for the increasingly more rapid development and maturation of follicles. Midgley postulates that many follicles fail to develop because the concentrations of FSH are insufficient to stimulate enough estrogen. The binding of FSH to its receptor also stimulates the follicle to develop LH receptors, and these permit the follicle to respond to LH by ovulating and becoming a corpus luteum. The corpus luteum produces progesterone to maintain pregnancy. As more is understood about follicular function and development, it might be possible to develop substances that would cause follicular atresia (involution of the follicle so that it is unable to release a functional ovum).

● Taking a somewhat different approach but working in the same general area are Cornelia P. Channing and Alexander Tsafriri of the University of Maryland School of Medicine, who are focusing on what causes the rupture of the follicle and release of the ovum. Channing reported that they appear



Monkey epididymis, enlarged many times.

to have demonstrated that, in the follicular fluid which bathes the ovum, there is an inhibitory substance which prevents in some way full follicular maturation. There may also be a second factor in follicular fluid that inhibits the luteinization (ability of certain cells to form a corpus luteum and secrete progesterone) of the follicle. They are trying to identify these factors, which might make it possible to develop a method of interfering with their essential roles.

The male reproductive process is also under scientific investigation, and the role of gonadotropins in gamete development is receiving attention in various laboratories.

● Frank S. French of the University of North Carolina Medical School is involved in clarifying the as yet unclear relationship of gonadotropins to spermatogenesis. The epithelium of the seminiferous tubules contains androgen target cells, Sertoli cells and others. FSH stimulates the Sertoli cells to produce androgen-binding protein (ABP) which, in turn, may increase androgen transport into the seminiferous tubules. Androgens augment FSH stimulation of Sertoli cells and maintain Sertoli cell function. Spermatogenesis requires Sertoli cell function. French's efforts provide a possible molecular basis for the belief that the interaction of FSH and androgen is necessary for spermatogenesis. Contraceptive methods which might develop from this information include inhibition of Sertoli cell response to FSH and inhibition of androgen binding to ABP or to receptors in target cells in the testis.

● The pivotal role of testosterone in spermatogenesis is being explored by Emil Steinberger of the University of Texas Medical School. His research, like that of others, suggests that the intratesticular concentration of testosterone must be many times that of the levels in the bloodstream to maintain spermatogenesis. Interference with the endogenous production of testosterone will stop sperm generation even though normal androgen levels remain in the bloodstream. Furthermore, normal circulating levels will not negate this effect because, Steinberger believes, FSH's role in spermatogenesis most likely is concerned only with its ability to permit testosterone to exert its effect.

● It is not yet known how just one sperm penetrates an ovum. An hypothesis extrapolated from observation of sea urchin eggs was put forward by David Epel of the Scripps Institution of Oceanography. His research suggests that there are special proteins on the outside of the membrane of the ovum, and these proteins are receptor sites for sperm. Once a sperm binds to a receptor site and penetrates the membrane, the cell is galvanized to release certain enzymes which digest the sites on the membrane, thus preventing other sperm from penetrating. He

Digest Ceases Publication

This is the last issue of *Family Planning Digest*. Reluctantly, we have had to discontinue publication of *Digest* despite its demonstrated effectiveness and usefulness for family planning professionals throughout the United States. The decision to discontinue was made in conformance with the Secretary's requirement that *all* DHEW publications must be sharply curtailed in this period when federal budgets are being cut back stringently.

A special "Digest" section, however, will be carried in a new, expanded *Family Planning Perspectives*, to be published six times a year by The Alan Guttmacher Institute (formerly the Center for Family Planning Program Development). The editorial staff of the Institute has been preparing *Digest* under contract to DHEW since its inception three years ago. I understand that the Institute will be informing *Digest* readers how they may receive *Perspectives*, so that they may continue to be informed about the most important new developments in the U.S. family planning field.

Back issues of *Family Planning Digest* may be obtained for as long as they last on a first come, first served basis from:

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Louis M. Hellman
Deputy Assistant Secretary for Population Affairs
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Human sperm, magnified x 5,250.

suggested two possible leads for contraceptive development: Interfere with the block to polyspermy so that many sperm may penetrate the ovum, thus disrupting the fertilization process; or close off the binding sites to prevent sperm binding.

Sources

Papers presented at the symposium on Advances in Fertility Regulation Through Basic Research, New York City, July 15-16, 1974:

W. A. Sadler, "Presumptive New Biological Sites for Fertility Regulation";

M. C. Chang, "The Contribution of Basic Science to the Development of Hormonal Contraceptives";

S. J. Segal, "The Role of Contraceptive Development in the Population Field";

M. Amos, "Fertility Regulation by Hypothalamic Releasing Factors";

O. P. Bahl, "Application of Gonadotropin Chemistry to Fertility Regulation";

B. W. O'Malley, "Steroid Receptors and the Regulation of Fertility";

M. Dufau, "Gonadotropin Receptors and the Regulation of Fertility";

A. R. Midgley, Jr., "Gonadotropin Receptors in Follicular Development";

C. P. Channing, "Regulation of Ovulation";

F. S. French, "Gonadotropin Support of Spermatogenesis";

E. Steinberger, "Steroid Suppression of Spermatogenesis"; and

D. Epel, "Egg Activation."

Other Source

B. Shearer, The Population Council, personal communication.

Developing Nations

Fertility Rates Decline Sharply After Countries Adopt Family Planning Programs

A "rapid fertility decrease" during the 1960s was reported for 12 developing countries with relatively vigorous, well-organized family planning programs that made available modern contraceptive methods such as the pill and IUD. Twelve comparable countries, which did not have vigorous programs or which discouraged family planning, showed little, if any, decline in fertility, or even recorded increases in fertility rates, despite the fact that there was "considerable social and economic improvement in a number of these countries." These findings were reported by Dr. R. T. Ravenholt, Director of the Office of Population of the U.S. Agency for International Development, and John Chao, Demographic Statistician with the Bureau of the Census. Their report, "World Fertility Trends, 1974," was published in the August issue of *Population Report*.

The authors observe:

> Although a number of factors may influence fertility over the long run—including education, per capita income, employment and status of women, availability of housing, jobs and the like—these latest data strongly suggest that over the short run for developing countries today the most important single factor in sharp fertility declines is the *availability* of more effective methods of fertility control distributed through vigorous nationwide family planning programs.

The authors note:

> Those countries with vigorous programs usually have a history of privately sponsored family planning activity for a number of years preceding active government involvement [in family planning].
>
> In most cases, at least five years must elapse between the initiation of a national family planning program and clear evidence of its impact on fertility.

They explain that this is because it takes about one year to recruit, train and deploy key leadership; a second year to recruit, train, employ and deploy service personnel; still another year to make services and information extensively available; nine months must elapse before conceptions prevented by contraceptives reduce births; and it takes at least a year to collect and analyze fertility data.

In Chile, for example, a private program began in 1962 and a government program in 1967. The period total fertility rate (TFR) of 5.2 children per woman at the program's start did not begin to decline significantly until 1966, but by 1970 it had gone down to about 3.7 per woman. (The TFR is the average number of children each woman would have if the age-specific fertility behavior in the year recorded remained the same over the woman's entire reproductive lifetime.) In Korea, a private family planning association was founded in 1961, when the TFR was 5.7 children per woman, and the government program began one year later. By 1970, the TFR had declined to 3.9. In Fiji, before the government program began in 1962, women could expect to have an average of nearly six children; by 1970, the TFR was down to 3.8 children per woman. In Egypt, where the government program began in 1965, the decline was less rapid, from a TFR of 6.3 in 1966 to one of 5.2 in 1970; but there was a one-third decline in the birthrates of women in their late twenties and early thirties—the age groups whose fertility had been highest. In Hong Kong, where the government began to support the private family planning effort in the mid-1960s, the TFR declined from 5.2 in 1961 to 3.5 in 1971. Other countries with vigorous, well-organized family planning programs where declines in the TFR occurred include Costa Rica, which registered a 38 percent decline; Mauritius, 41 percent; Puerto Rico, 30 percent; Singapore, 49 percent; Trinidad and Tobago, 38 percent; and Taiwan, 41 percent.

Dr. Ravenholt and Mr. Chao noted that the 12 developing countries with no or only incipient family planning programs, in which the government provided little or no support or even discouraged family planning, showed minimal or no declines in fertility (Brazil, Ecuador, Ivory Coast, Kuwait, Mexico, Paraguay, Peru and Venezuela), or even registered small increases (Algeria, Ghana, Nicaragua and Syria).

"These latest demographic data challenge the hypothesis that only antecedent social and economic development can produce a decline in birth rates," the authors declared, explaining that:

> Brazil, Mexico, and Kuwait, for example, all experienced very high rates of economic growth in the 1960s; individual income did increase, although at the lower socio-economic levels it may have been partially cancelled out by high birth rates. But in the absence of family planning programs and ready access to improved means of fertility control, these socio-economic gains were not translated into lower birth rates.

Although all countries with crude birthrates below 20 per 1,000 population are highly developed, some of the developing nations are approaching this level, and they assert:

Women at a Singapore family planning clinic.

these latest fertility data suggest that many less developed countries may soon move into the lower fertility category even before they move into the more developed category. Such antecedent decreases in fertility and population growth should greatly facilitate and speed their further economic and social development and in particular should help to insure that any increases in gross national product are at least in part shared by the existing population and are not entirely consumed by new population growth.

Examples of less developed countries nearing the 20 per 1,000 population mark in crude birthrate are Barbados (20), Hong Kong (19), Mauritius (23), Taiwan (24), Cyprus (22), Singapore (23), Uruguay (23) and Bermuda (21). All have vigorous family planning programs.

Source

R. T. Ravenholt and J. Chao, "World Fertility Trends, 1974," *Population Report: Family Planning Programs*, Series J, No. 2, Aug. 1974; and J. Chao, personal communication.

Population

How Can States Guide Their Growth?

What legislative options are open to a state that wants to control its population growth and distribution? The possibilities include fertility-related laws that would make contraceptive services and abortion readily accessible, land use control policies, subsidization of day care centers, equal opportunity employment legislation and state promotion of industries that rely on female labor, according to R. Kenneth Godwin, Assistant Professor of Political Science at Oregon State University and Visiting Scientist at Battelle Population Studies Center. As with all legislation, any of the options, Godwin explained, has its own special political problems which would have to be addressed in order to make the proposals acceptable to legislators and the electorate.

Legislation dealing with abortion and contraception most directly affects fertility, Godwin pointed out, suggesting "an increased program to distribute free or low-cost contraceptives and contraceptive information to potential users. Ideally, this would be coupled with meaningful health service reform." While the Supreme Court decisions declared antiabortion laws unconstitutional, ready access to legal abortion is still a problem for some women, he said. In his home state of Oregon, Godwin noted, women who live in rural areas have access problems "because there are fewer hospitals in the less populated areas and the hospitals in these areas have been reluctant to allow abortions." Therefore, women in these areas must travel some distance for an abortion, adding to the costs.

Less direct methods of affecting fertility behavior involve programs with political drawbacks, Godwin noted. Educational and propaganda programs supporting smaller family size and sex education in public schools "are quite controversial and would be likely to arouse strong and vocal opposition."

Even more indirect in approach are programs aimed at increasing employment opportunities for women from low-income, high-fertility groups in the hope that the income the women would earn would make the "cost" of additional children—in terms of lost wages—high enough to dissuade many women from further childbearing. One approach would be to strengthen equal employment legislation. This "could increase employment of women and possibly increase the incomes of Blacks, Indians, and Chicanos." Increased income for minorities in general "might reduce the birth rates of these groups. [This] reduction would occur if the groups adopted the white, middle-class norm of a small family."

Such a trend toward convergence of the fertility patterns of ethnic minorities and urban whites between 1960 and 1970 has already been noted by James Sweet, along with the closing of the income gap between these groups. [See: "Fertility Decline More Rapid among U.S. Minorities than among Urban Whites," *Digest*, Vol. 3, No. 4, 1974, p. 12.] The establishment of day care centers would also encourage more women to work, Godwin observed. He explained that "when day care centers are available, women who previously would not have considered working because the income gained after the expenses of child care were deducted was less than the costs of working" would enter the labor force. They would then be reluctant to leave the labor force to bear another child.

Programs of the type described, despite their beneficial aspects, "suffer from the same political weakness—they are designed to benefit the 'politically disadvantaged'," Godwin maintained. "The poor, and until recently women, . . . have lacked cohesion, economic resources, and sufficient *individual* benefit . . . to make them a strong political force. Thus, it would appear that unless these groups can join with other political forces, the possibilities for the passage of most of the measures are not good."

Sex education programs do have political support from some groups—primarily medical and educational. "In addition, the spread of venereal disease may have reached the crisis proportions necessary to insure the passage of a bill." Another approach that would have strong support would be "the development of an incentive program [with tax credits and subsidies] to attract industries requiring female labor." This approach could be useful "in sparsely populated areas where household incomes are low and dependency ratios, unemployment, and birth rates are high."

There are two major approaches to dealing with population distribution—discouraging growth in certain areas, encouraging it in others—according to Godwin, through state land use regulation and the development of "growth centers." Land use control, by appropriate zoning, can promote or discourage industrial growth, and can also affect population densities. In addition to affecting population issues, land use legislation can have profound effects on environmental, racial and economic issues, Godwin noted, and local groups might be strongly opposed to such statewide regulatory power. They might create political stumbling blocks to such plans.

The growth center concept would also face political problems. Basically, the program would consist of some form of subsidies to relatively major communities in less populated areas, with the aim of spurring enough growth to improve the economy of the area. If successful, migration to more populated areas would be discouraged and migration from such heavily populated areas would be encouraged. However, other areas of the state not benefiting from such subsidies would eventually demand similar subsidies—which could lead to growth where it is not desired.

Source

R. K. Godwin, "Population Policies Available to the State of Oregon," paper prepared for the Rockefeller Foundation-sponsored project, "Man and His Activities as Related to Environmental Quality," Aug. 1973.

Teratogenic Effects?

Oral Contraceptives, Some Pregnancy Tests May Increase Risk of a Rare Birth Defect

An association between ingestion of sex steroids—including oral contraceptives—and an increased risk of bearing a child with congenital limb reduction (an extremely rare type of birth defect) is suggested by research reported in the *New England Journal of Medicine*. The incidence of limb reduction, which involves the absence of a limb or part of a limb, including fingers and toes, is reported by investigators from the Birth Defects Institute of the New York State Department of Health as occurring in one of every 5,000 live births in the state between 1968 and 1973. Of 108 cases of the defect investigated, the authors found that 15 of the mothers had been exposed to sex hormones early in pregnancy, compared to only four in a matched control group. The study was reported by Dr. Dwight T. Janerich, Joyce M. Piper and Donna M. Glebatis.

Dr. Janerich and his colleagues located and interviewed the mother by telephone in 108 of 190 cases of congenital limb reduction reported to New York State's Congenital Malformation Surveillance Program between 1968 and 1973. Thirty-seven mothers could not be reached, and 45 stillbirths, illegitimate births and adoptions (as well as all New York City births) were excluded from the survey. (The group reached represents 82 percent of those considered appropriate for the study, and 57 percent of the total number of women in the time period concerned known to have borne children with limb anomalies.) Controls for the retrospective case control study were selected by choosing the closest birth in county records (without a limb reduction defect) for which the mother was of the same race and within two years of age of the case mother in question. The women's doctors were first queried as to whether the mothers could be interviewed for the study, and were questioned again to verify those cases in which the mother could not be certain about what drugs she had taken during pregnancy.

In six of the cases of congenital limb reduction, the pregnancy had occurred while the mother was using oral contraceptives (one using a sequential preparation and five using combination pills with 50 mcg of estrogen), compared with just one of the controls. (One other control mother began pill use by mistake after she had become pregnant.) Six of the women who gave birth to defective children had taken hormones to help maintain their pregnancies, compared with one of the control mothers; and three of the case mothers had been given progestogens as a pregnancy test, compared with one control mother. In all the cases and all but one of the controls, the hormones were taken during the first trimester of pregnancy. Fifteen mothers of affected children became pregnant within three months of stopping the pill, compared with only six control mothers. According to Janerich and his colleagues, their data suggest that women who take steroids early in pregnancy may be 4.7 times more likely to bear a child with a congenital limb reduction defect than women who do not do so.

Two Population Council researchers, Jonathan T. Lanman and Anrudh Jain, did a further analysis of Dr. Janerich's data to evaluate the separate effects of oral contraceptive use during pregnancy, conception shortly after oral contraceptive discontinuation, and administration of other hormones during pregnancy. They said that the data suggest that mothers who become pregnant while taking the pill run a risk of bearing a child with a limb reduction defect 7.3 times greater than that of women who do not take pills for at least a year (6.9 per 10,000 births compared with 0.9 per 10,000 births). For offspring of women who become pregnant within three months of stopping pill use, there might be a threefold increased risk (2.9 per 10,000 births) and, for women exposed to other hormones, the relative risk might be close to four times as great (3.4 per 10,000 births).

Assuming an incidence of one birth resulting from an accidental pregnancy occurring during pill use per 100 pill users per year, "the incidence of affected births in the absence of induced abortion would be about seven per million users of oral contraceptives per year," Lanman and Jain calculate. Thus, some 60-70 babies per year could be affected in the United States, if the Janerich data prove to be applicable.

Male Children Affected

One unexplained observation was that, among the birth defect cases, all six children of mothers who became pregnant while using oral contraceptives were male. In addition, all of the five women given hormones for other reasons, who took the hormones orally, had boys. Of the remaining four women who received hormones only by injection, three had girls. Three of the four control mothers who received hormones during pregnancy also had girls. The authors comment: "This strong association between oral ingestion of sex steroids and affected male children . . . seems to imply that these hormones have some type of sex-specific effect on the developing fetus." This sex specificity was not seen, however, among the six affected cases in which the mothers conceived within one month of discontinuing the pill. Dr. Janerich told *Digest* that there appear to be two different effects involved—one, sex-related, in which the hormones are ingested orally during pregnancy, and the other, not sex-related, when they are taken shortly before conception.

Since ingestion of sex hormones during pregnancy is associated with only a statistically small increase in risk that a defective child will be born, Dr. Janerich and his colleagues conclude that:

> some type of maternal predisposition is probably necessary before exposure can lead to a malformed offspring. This might explain how hormone exposure during gestation can sometimes be harmful, and why it does not always lead to gross malformation. Further study of this matter is essential.

In an editorial on the subject in the same issue of the *New England Journal of Medicine*, Drs. James J. and Audrey H. Nora of the University of Colorado Medical Center support this view, pointing out that available data from other studies into the effects of progestogens and estrogens on birth defects

> suggest that, if progestogen/estrogen produces malformations, it is at a low frequency rate probably acting on predisposed persons. The epidemiologic impact of these hormonal agents would thus not be related to high risk for individual exposure, but to the high number of exposures from widespread use.

The Noras had previously reported two sets of observations linking sex steroids with an increased risk of birth defects. Twenty of 224 patients with congenital heart disease had been exposed to sex steroids during "the vulnerable period of cardiogenesis," compared with only four of 262 controls. In addition, they reported that eight of 12 patients with multiple congenital anomalies of various types had been exposed to a progestogen-estrogen combination or progestogen alone during embryogenesis. The Noras as well as the Janerich group also referred to previous reports in the literature of a possible association of the use of hormonal preparations and other types of congenital malformation.

Janerich and his colleagues agree with the Noras that these data indicate "it is prudent to discontinue the use of hormonal pregnancy tests."

The Population Council investigators pointed out some possible shortcomings of the study. They noted that only 57 percent of all recorded cases were followed up, and questioned the appropriateness of a telephone interview with the mother without examination of the child "or examination of the concordance between the mother's recollection of her contraceptive history and

the obstetrician's record taken at the time of pregnancy."

Sources

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Law

47 States Permit Unwed 18-Year-Olds to Obtain Their Own Birth Control Services

As of mid-1974, the right of unmarried 18-year-olds to consent to most kinds of medical care (including contraception) has been affirmed in 47 states and the District of Columbia, and for pregnancy-connected care in all states except Wyoming and Nebraska, where the minimum age is 19. Unmarried teenagers younger than 18 may consent for their own contraceptive services in at least 24 states and the District of Columbia, and for abortion in 17 states and the District. Minors under 18 may consent for VD treatment in all states but Wisconsin and Hawaii where the minimum age is 18. This affirmation of the right of teenagers to consent for their own medical care is related, in part, to the fact that 41 states have reduced the age of majority to 18 and, in part, to growing acceptance of the "mature minor rule." Under this 'rule', if a minor is sufficiently mature to understand the nature and consequences of the treatment proposed, and such treatment is for his or her benefit, the minor has the right to consent for such treatment.

These are some of the findings of an analysis of laws concerning teenagers, pregnancy and medical care by Eve W. Paul, Harriet F. Pilpel and Nancy F. Wechsler, published in *Family Planning Perspectives*. This "liberalizing trend" in legislation relating to minors is typified by the enactment in recent years of laws in 13 states and the District of Columbia specifically allowing minors to consent for their own contraceptive services, the authors point out, while a dozen other states have passed laws authorizing government-funded family planning programs to provide services at least to some minors without parental consent.

"The trend has been consistently in the direction of liberalization of laws affirming the right of young people to consent for their own contraceptive care," the authors note. While minors could consent to such services in at least 24 states and the District of Columbia as of mid-1974, "just five years before, there was virtually no state in which this right was clearly affirmed by statute." [By mid-1972, 18 states (plus the District) affirmed the right of minors under 18 to consent to contraceptive services. See: "Girls under 18 Can Consent to Birth Control Services in Two-Fifths of the States," *Digest*, Vol. 1, No. 6, 1972, p. 1.]

Without specific laws affirming a minor's right to consent for his or her own health care, many physicians are reluctant to provide such care without prior parental or guardian consent. Their anxiety stems from the old common law rule that minors are not competent to consent for their own medical care, and that provision of services may make the doctor liable in damage suits. The authors point out, however, that, to their knowledge, no physician has ever been held liable for damages for providing *any* beneficial medical service to a minor aged 15 or older on his or her own consent, or for providing *contraceptive* services to a minor of *any* age.

Because of physician concern, however, many states have considered it necessary to affirm the rights of minors for health services —especially sex-related services—by statute, attorney general's opinion or court action. Some of the states that have laws confirming the rights of minors to consent for contraceptive care specifically exclude abortion and sterilization. [Under a recent court ruling, no federal funds may be used for the sterilization of minors. See: "0.2% of Patients Under 21 in U.S.-Funded Family Planning Programs Sterilized in 1972," *Digest*, Vol. 3, No. 4, 1974, p. 10.] The three states in which no law affirms the right of an 18-year-old to consent for his or her own contraceptive services are Nebraska, Wyoming (where they must be 19) and Missouri (21).

Because of the Supreme Court's *Roe* v. *Wade* and *Doe* v. *Bolton* abortion decisions, and the lowering of the age of majority to 18 in most states, 18-year-olds may obtain abortions in all but two states (Wyoming and Nebraska, where they must be 19). "But the girl who is younger than 18 and pregnant may face formidable obstacles in obtaining abortion without parental consent," the authors observe. While no state law specifically bars provision of contraceptive services to minors, several states require parental consent for a girl under 18 to obtain a legal abortion. But several such laws have been challenged in the courts, and federal district courts in Florida and Utah have ruled unconstitutional state laws requiring parental consent for abortions to minors.

In court decisions in the District of Columbia and New York, the "mature minor doctrine" was successfully invoked to justify abortions on a minor's own consent.

Source

E. W. Paul, H. F. Pilpel and N. F. Wechsler, "Pregnancy, Teenagers and the Law, 1974," *Family Planning Perspectives*, **6**:142, 1974.

Resources in Review

By Dorothy L. Millstone

Although a stream of recent reports from visitors to mainland China provides information on official policy concerning family planning and on contraceptive development and distribution, there have been no authoritative first-hand reports on how the Chinese consumer is educated. Now a Kwangtung Province manual (dated 1972), translated and published by the American Universities Field Staff, makes it possible for American family planners to learn how their opposite numbers in China present the theory and practice of birth limitation.

• The manual, *Delayed Marriage and Planned Birth* (8½" x 11", 1973), in general conforms to a familiar format. Five of its six chapters are typically found in American counterparts: advantages of planned birth, physiology of pregnancy and contraception, methods of contraception, abortion and sterilization.

Not surprisingly, it is the philosophic base, the rationale for spacing and limiting births, that reveals the principal Chinese distinction. Delayed marriage and family planning are advocated as a basic requirement of the socialist revolution and socialist reconstruction. The official goal is clearly stated: to change the former fertility pattern of "early, frequent and many" births to "late, spaced and few." [p. 2] The prime motive also is plainly put: to control population. Says the manual: ". . . in this way we can change the situation in population growth from one which is unplanned to one which is planned, and thereby better adapt to the needs of the planned and proportional development of the national economy, and improve the people's health." [p. 2]

The two-child family is recommended, with four to five years between the two births.

From there on, the Chinese case for family planning—although cast in the vocabulary of revolution—closely parallels the reasoning in American manuals. Stress is placed on benefits to maternal and child health, women's liberation and greater educational opportunity for children. The small family is seen as a key to raising living standards.

There are some surprises in the material on methods. Condoms, for example, come in three sizes: large, medium and small. The instructions on oral contraceptives mention such side effects as nausea and vaginal bleeding, but say nothing about the danger of thromboembolism. Both intrauterine devices described are of the closed variety, no longer approved in the United States. The diaphragm, contraceptive foams, creams and gels, and rhythm are not mentioned. Abortion is available. It is considered a remedial technique for failed contraception and repeated abortion is described as harmful to health.

One puzzling note: The assertion is made that "Men and women will not be fully grown until about the ages of 25 and 23 respectively." [p. 3] It is then alleged that "since the bone structure of a woman under the age of 23 is not fully mature, the pelvis is rather small, the musculature of the uterus is not yet well developed, and she is more likely to have a difficult labor." [p. 3] Whether ideology is rewriting physiology remains for the comparative anatomist to clarify, but we are skeptical.

This is probably one of many provincial family planning manuals—not *the* Chinese manual. Because it is a guide to one of the very few successful programs in nations with substantial population growth, many will find it worthy of study.

Cost of the manual is $1. To order, write the American Universities Field Staff, P.O. Box 150, Hanover, N.H. 03755.

For Communicators

• The suggestion that family planners consider commercial channels to help bring patient and service together, while not new, is worth considering. *Questions and Answers about Commercial Resources for Family Planning Communication Programs* (28 pp., 4" x 9", 1974), by Douglas S. Solomon, persuasively champions this proposal. The booklet, published by the East-West Communication Institute, recommends that advertising agencies, market research organizations and direct mail specialists be consulted. It recounts successful case histories of this procedure from around the world and reproduces striking samples of their advertising. Most of this material is applicable to health education in general but its experience and illustrations are all drawn from family planning.

For a free sample copy, write the East-West Communication Institute, 1777 East-West Road, Honolulu, Hawaii 96822.

Where Sterilization Is At

• *Voluntary Sterilization* (1974), a new 5" x 7", 28-page Public Affairs pamphlet by Elizabeth Ogg, is authoritative, comprehensive, lucid and interesting. It is both a handy general reference for those seeking data on trends in acceptance, current methods, impact, availability and costs, and a good guide for individuals considering permanent birth control. The questions people ask most often are answered. Newer techniques, such as laparoscopy and culdoscopy, are described.

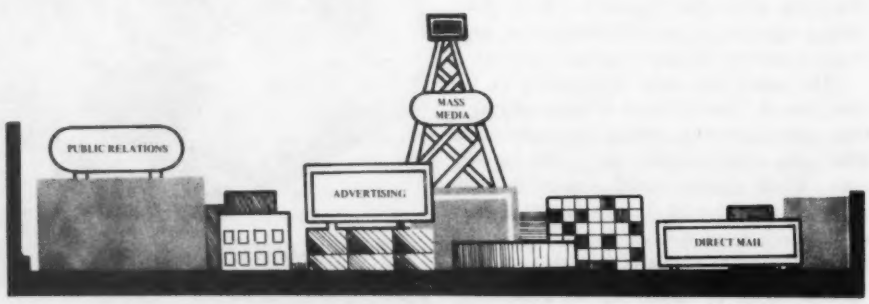
A single copy costs 35¢, and orders in quantity carry a discount. Order from Public Affairs Pamphlets, 300 Park Ave. South, New York, N.Y. 10016.

At the Marriage License Bureau

• *Marriage Manual*, a new 4" x 9" folder prepared by the Georgia Department of Human Resources for presentation to each couple as they receive a marriage license, is worth seeing. Family planning is the first of 10 important subjects briefly covered. The paragraph on family planning, headed "Babies," says: "You may want children. You may not. Or, most likely, you want to have the number of children you want at a time when both of you are ready." It goes on to indicate where to get information. Understatement is a virtue of this publication. It is essentially a one-page flyer printed on both sides and folded into six panels so that it fits into a number 10 envelope. Art, type and design take inspiration from today's nostalgia fashion and harmonize well with its appropriate low-key tone.

The other subject areas are pregnancy, health, taxes, free services, counseling, nutrition, consumer protection in purchasing, budgeting, and what to do if victimized by fraud.

The folder is being widely used. A Department of Human Resources telephone information service, listed on the back page, has more than doubled the Department's



The various mass media shown in this illustration from: "Questions and Answers About Commercial Resources for Family Planning Communications Programs," the East-West Communication Institute.

calls since distribution began. This is a switchboard service which actually plugs the caller into the agency whose service is required and permits a three-way conference call on the spot. As a result, people who want to know where and how to get family planning can actually talk to the clinic or service nearest them and make an appointment on just one call. Other health and consumer problems are handled in the same way.

A free sample can be obtained by writing to the Georgia Department of Human Resources, 47 Trinity Ave., S.W., Atlanta, Ga. 30334.

By Students for Students

• Spunky, impudent art, charming beyond all expectations, and refreshingly practical advice adaptable to any high school, characterize *The How-To Handbook* on organizing a student sex information project.

The Student Coalition for Relevant Sex Education, which published this 24-page, 5½" x 8½" booklet in 1974, actually organized such a program in New York City and its efforts have led to a flourishing teacher-student cooperative enterprise. Undoubtedly, it is this down-to-earth experience that endows the manual with its thoroughly businesslike style. Its freedom from verbosity is a model.

The material covered fits the title; it is *all* about organizing. The objective of a sex information project for students is "to provide the necessary information in the area of human sexuality, to enable young people to grow into informed, healthy, responsible adults," [p. 1] according to the booklet's authors.

Separate sections tell how to enlist student, faculty and parental support, as well as how to work with a council of students, teachers, parents and the principal. Step-by-step action is outlined. Other sections deal with getting space and using it, training student leaders and faculty advisors, opening and running a rap room and keeping the program going.

A small fraction of the material is applicable only to New York City schools; for example, references to teachers' union rules won't necessarily apply uniformly. Otherwise, its guidelines seem easily adaptable and calculated to win faculty and parental support.

Although inexpensively produced (basically typewritten, duplicated, with pages stapled together), the booklet is more interesting than many bound volumes. An introduction offers to send further information about the Student Coalition to those who write.

The *How-To Handbook* costs 50¢ a copy. To order it, and to learn more about the project, write the Student Coalition for Relevant Sex Education, 300 Park Ave. South, 4th Floor, New York, N.Y. 10010.

Counseling Teenagers

• *How to Talk to Your Teenagers About Something That's Not Easy to Talk About* is a Planned Parenthood publication addressed to adults. But it could also be comfortably and profitably used by many teenagers. Its friendly, nondogmatic tone helps defuse a sensitive subject. Its method is to provide brief answers to selected questions commonly asked about sex, reproduction and contraception. Family planning methods are described. Those available only from a doctor are distinguished from those obtained from a drugstore without a prescription. But no attempt is made to tailor family planning information to teenagers' special needs.

Selected book lists for young people and adults, as well as a directory of organizations and their addresses, indicate where the reader can get additional information.

This booklet (24 pp., 3¾" x 9", 1974) costs 25¢ a copy; larger orders command discounts. Order Publication No. 1436 from Planned Parenthood Federation of America, 810 Seventh Ave., New York, N.Y. 10019.

Playing in Earnest

• *Lifestyle* is a simulation game suitable for high school and college-age students in a variety of settings, including teen family planning clinics, counseling rap sessions, sex education courses, and community health and family life education projects. School social studies, home economics and health courses would also find it interesting.

The aim of the game is to encourage the student to indicate preferences in important life decisions such as education, marriage, family size, housing, career, income aspirations and recreational goals, and to put a price tag on individual components of choice as well as on the full packet.

A boy and girl pretend to be engaged. They reply to a series of questions probing their aspirations and they record their decisions on a playing board and in a record book. This gives them a measure of the feasibility of their first "plans" (perhaps 'dreams' would be a more appropriate term). The question of family planning is one of four major issues under consideration. On the average, it takes about an hour and a half for a couple to play the game. In a classroom situation, most of the students would be listening and participating in a discussion after the role-playing was over.

The game's frame of reference is narrow and materialistic. Income and outgo set the parameters for choices. But that is realistic. Less firm is the game's economic base. Its assumptions of earning capacity keyed to education endow the individual with more control over his fate than many experience in real life.

But this is a game, though a meaningful one, and no one will take it amiss that some jobs now carry salaries quite different from those the game assigns. The message of the game is planning, in all areas of living, including the number and spacing of children. A teacher's manual, a player's manual, fake money and credit chips are part of the set's equipment.

The game sells for $19.95. A free sample (everything but the playing board) will be sent on request to *Digest* readers. Write to Educational Methods, 500 North Dearborn St., Chicago, Ill. 60610, Attention: Jason A. Nogee.

For Educators

• In the United States, where sex is used to sell everything from autos to shampoo, and TV, the movies and the print media are increasingly uninhibited about portraying sexual activities, teachers and counselors are still being trained as if adolescents were "sexually dormant." This finding led Marianne Mitchell, professor in Indiana University's Department of Counselor Education, to write a monograph, *The Counselor and Sexuality* (83 pp., 6" x 9", 1973). She notes that not one of the states licensing school counselors makes mandatory teaching knowledge, experience or skill in this field. Moreover, a review of the curriculum of 40 counselor training centers failed to reveal any required courses in sexuality. Her monograph is a reasoned exposition of the need for: systematic and developmental school sex education; a review of the common sexual concerns of young people; an examination of the counseling function in sexuality; and the presentation of a model program coordinating classroom education and counseling. Family planning is included, without emphasis, in recommended sex education.

Because the monograph's approach assumes administrative commitment, schoolwide support and coordination with counselors, its prime audience may be school superintendents, principals and executives of agencies seeking to foster better school programs rather than would-be counselors,.

The book costs $1.35 and is published by Houghton Mifflin as part of its Guidance Monograph Series, Series VII, Special Topics in Counseling. Order from your bookseller or from the publisher.

Correction—West Coast readers seeking information about the film, *Life World 2000* (reviewed in "Resources," Vol. 3, No. 4, 1974, p. 9), should write to the National Instructional Television Center's regional office at 1670 S. Bayshore Blvd., Suite 101, San Mateo, Calif. 94402.

IUDs

Risk of Ectopics Increases with Time

The risk of ectopic pregnancies to women wearing IUDs may increase with the length of time a woman has worn the device, according to an analysis of the outcome of 927 pregnancies reported from 17 family planning clinics in England and Wales. The study by Dr. Martin P. Vessey, Sir Richard Doll, Bridget Johnson and R. Peto of the Radcliffe Infirmary at Oxford, published in *The Lancet*, also showed that more than half of all pregnancies that occurred with an IUD in place (and that were not terminated by induced abortion) ended in miscarriage.

Since 1968, there have been 320 singleton, unplanned pregnancies among the parous women from 17 clinics enrolled in an ongoing prospective study of the beneficial and harmful effects of various contraceptive methods. All the women were married, white British subjects, and were aged 25-39 when they enrolled.

Of 39 conceptions that occurred up to two years after IUD use began, one (2.6 percent) was ectopic. Similarly, one of 28 conceptions (3.6 percent) that occurred in the third and fourth year after IUD use started was ectopic. However, of 23 pregnancies that occurred after four or more years of IUD use, six (26.1 percent) were ectopic. The researchers warned that their "new finding" of a "positive association between the duration of use of an intrauterine device and the risk of ectopic pregnancy if the device should fail . . . is based on very small numbers and the conclusion is uncertain."

Miscarriage

Among the women, there were 605 planned pregnancies that were not terminated by induced abortion. Of 58 such planned pregnancies among women who had previously used IUDs, 10 (17 percent) ended in miscarriage, as did 62 (11 percent) of the 547 pregnancies among women who had been using other contraceptive methods. Although the miscarriage rate was slightly higher among former IUD wearers, the difference was not statistically significant.

Among women using methods of contraception other than the IUD, the miscarriage rate was slightly but not significantly higher when the pregnancies were unplanned (17 percent) than when they were planned (11 percent). A much different picture emerges, however, among women who became pregnant while wearing an IUD. There were 34 miscarriages in 65 cases in which pregnancy occurred with an IUD in place (and was not terminated by induced abortion)—a miscarriage rate of 52 percent. This rate among IUD wearers was significantly higher than the rate for users of other contraceptive methods. Other researchers have reported a similar high miscarriage rate when pregnancy occurs with the IUD in place, and have suggested that removal of the device would lower the rate. [See: "IUD Removal May Avert Miscarriages," *Digest*, Vol. 3, No. 2, 1974, p. 13.]

"We conclude that unplanned pregnancies occurring in women with an intrauterine device in situ have an extremely unfavorable outcome," the investigators observed, "both in terms of ectopic gestation and miscarriage. While the miscarriage of an unplanned pregnancy may be welcomed, the event is not without risk; ectopic pregnancies, of course, are notoriously hazardous. Women conceiving while using an intrauterine device therefore require close supervision if tragedies are to be avoided."

Source

M. P. Vessey, R. Doll, B. Johnson and R. Peto, "Outcome of Pregnancy in Women Using an Intrauterine Device," *The Lancet*, **1**:495, 1974.

Copper IUD

Blood Loss Lower Among TCu Users

Women using copper IUDs have, on the average, less than two-thirds the menstrual blood loss experienced by women using the Lippes loop, according to a study of 336 women attending the family planning clinic of Al-Azhar University Hospitals in Cairo, Egypt, reported in *Contraception*. The menstrual blood loss by women using the Copper T (TCu-200) and Copper 7 (Cu-7) is still one-third greater than that of women using no contraceptives, however, the investigators reported, and is two-and-one-half times that of women taking oral contraceptives.

Included in the study were 91 women using copper IUDs (77 TCu-200s and 14 Cu-7s), from whom menstrual blood was collected in cotton pads for 349 cycles; 50 women using the Lippes loop C, with 224 cycles collected; 50 women using combination pills, with 236 cycles collected; and 145 normal controls, with 240 cycles collected. The average blood loss per cycle was 20 ml for pill users, 37 ml for controls, 49.8 ml for women wearing copper IUDs and 78 ml for women using the Lippes loop.

There was a significant decline in the blood loss with the copper devices over time, the researchers observed. During the first cycle after insertion, the average blood loss in this group was 62.2 ml. After three months, this had declined to 50.8 ml, and continued to decrease to 42 ml after six months, 39 ml after nine months, and 37 ml—the same as the controls—after 12 months. One factor contributing to the decline, however, was the fact that several women who suffered from excessive menstrual blood loss had their IUDs removed and dropped out of the study. The average loss during the first cycle was especially high, the investigators noted, because 15 women—eight of whom had switched from the Lippes loop—had menstrual blood loss greater than 80 ml.

Poor women in both developed and developing countries run the risk of developing anemia because of iron-deficient diets, the authors point out, and the risks are greater when a contraceptive increases blood loss. They noted that menstrual blood loss is lowest with the pill; but among IUDs, "copper devices [are associated with] the least menstrual blood loss . . . and hence are most suitable in developing countries, especially since their contraceptive efficacy is still highly reliable."

Similar findings were reported by investigators from the University of Southern California School of Medicine. In a study of 227 women, fairly evenly divided among the Copper T-300 (TCu-300), the Dalkon shield and the Lippes loop D, the investigators found that women using the TCu-300 had the lowest menstrual blood loss—54.5 ml after six months of use, dropping to 49.8 ml after 18 months. Women using the shield had an average blood loss of 60.4 ml at six months, 74.7 ml at 12 months and 65.6 ml at 18 months, while women wearing the Lippes loop D (slightly larger than the one used in the Egyptian study) had average menstrual blood losses of 75 ml at six months, 56.5 ml at 12 months and 63.7 ml at 18 months. A smaller proportion of women using the TCu-300 had menorrhagia (excessive blood flow) than did users of either of the other devices.

Sources

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R. Israel, S. T. Shaw, Jr., and M. A. Martin, "Comparative Quantitation of Menstrual Blood Loss with the Lippes loop, Dalkon shield, and Copper T Intrauterine Devices," *Contraception*, **10**:63, 1974.

Effective Methods

More Pill, IUD Use Cuts Unwanted Births

Increased use of the pill, the IUD and sterilization by women who do not want any more children would cause dramatic declines in the rate of unwanted births in the United States, according to an analysis by J. Richard Udry and Karl E. Bauman of the Department of Maternal and Child Health of the University of North Carolina at Chapel Hill. If 70 percent of women who

have had all the children they want used these methods, instead of the 45 percent who are currently using them, unwanted fertility would be reduced by about 30 percent.

The calculations are based on interviews conducted in 1969 and 1970 with more than 3,100 women from low-income areas of 17 U.S. cities. Data from 1,021 black and 795 white women who said they wanted no more children were used in the analysis. Among the white women, 45 percent were using the more effective physician-administered methods (of whom 36 percent were relying on sterilization), with the remainder using traditional methods or no contraception at all. Among black women, 47 percent were using the more effective physician-administered methods (of whom 26 percent relied on sterilization).

The failure rate among white women using the more effective methods was 2.5 per 100 woman-years, and was 14.8 among those using traditional methods or no method. Among blacks, the failure rates were 4.6 per 100 woman-years for those using the more effective methods and 22.0 for the others. Therefore, the overall failure rate for whites, with 45 percent using the more effective methods, was 9.3 unwanted births per 100 woman-years; and for blacks, with 47 percent using the more effective methods, the rate was 13.8 per 100 woman-years. If the proportion of women using the pill, IUD and sterilization increased from 45 percent to 70 percent, the failure rate for whites would drop to 6.2 per 100 woman-years (a decline of 33 percent), and for blacks to 9.8 per 100 women-years (a drop of 29 percent).

In addition, if a larger proportion of women using the more effective methods relied on sterilization, rather than the pill or IUD, the failure rates would decline still further, the authors pointed out. For example, if 70 percent of women who wanted no more children were using the more effective physician-administered methods, and if 70 percent of these women relied on sterilization (rather than the 26 percent of blacks and 36 percent of whites among the women in the survey), the failure rates would drop an additional 15-20 percent, to 7.9 per 100 woman-years for blacks and 5.2 per 100 woman-years for whites.

If all women who wanted no more children were using the more effective physician-administered methods—with no increase in the proportion using sterilization—the failure rates would drop by about 70 percent overall, for both black and white women.

Source

J. R. Udry and K. E. Bauman, "Effect on Unwanted Fertility of Extending Physician-Administered Birth Control in the United States," *Demography*, 11:189, 1974.

Teen Education

'Rap' Session with Teenagers Improves Knowledge of Contraception, Abortion, VD

A "rap session" run by Planned Parenthood of Detroit helped to increase markedly teenagers' knowledge of contraceptive methods, abortion and venereal disease, Paul A. Reichelt and Harriet H. Werley of the University of Illinois Medical Center (Chicago) reported at the last annual meeting of the American Psychological Association.

The rap sessions were conducted at the Planned Parenthood affiliate's Youth Education on Sex (YES) Teen Center, which provides free nonprescription contraception for males and females, medical contraception and related services for women under 18, and sex education for both male and female teenagers. The group studied included 367 girls under 18 who returned to the teen center for oral contraceptives. The girls ranged in age from 14 to 17, with a mean age of 16.2 years. Three-quarters of them were white, the rest black. Slightly more than half lived in the city of Detroit, with the remainder coming from the surrounding metropolitan area. The majority of the girls came from middle- and lower-income homes, and 86 percent of them were sexually experienced. Of those who were sexually experienced, 76 percent had used some form of contraception at least once. All the teenagers completed a questionnaire focusing on contraception, abortion and VD before attending the rap session, and were given a similar questionnaire about 10 weeks later when they returned for contraceptive supplies. (Attendance at the educational rap session is required before a teenager can receive contraceptive services. After the rap session, teenagers who select the pill are given an interim method such as condom and foam, and an appointment is made for them, usually within two weeks, for the required physical examination. After their physicals, they are provided with a two-month supply of pills. They are then required to return to the clinic for a supply visit. If all is well, they are given a five-month supply of pills.)

All questions were in a true-false format. Six questions concerned oral contraceptives. Before the rap session, teenagers' correct answers ranged from a high of 79 percent to a low of 35 percent. The question to which almost four out of five respondents replied correctly was: "The pill is the most effective method of birth control" (true). The question which elicited the fewest correct answers was: "The pill may be taken along with other medications without decreasing its effectiveness" (true). On the retest, correct responses to the two questions were 95 percent and 63 percent, and similar improvements in knowledge were achieved for the other four questions about the pill.

A marked improvement also occurred on questions concerning the IUD. Originally, correct responses ranged from a low of only 24 percent who knew that "the IUD usually works best if the uterus (womb) has been stretched by a previous pregnancy," to a high of 41 percent who knew that "the IUD is [not] inserted before each act of intercourse." The second time around, 46 percent knew the answer to the first question, while 77 percent replied correctly to the second. As with the pill, marked improvements were also achieved on the other questions.

To the four questions dealing with the diaphragm, correct responses ranged from a low of 37 percent who knew that "effectiveness of the diaphragm is increased when used with a cream or jelly," to a high of 62 percent who knew that "a diaphragm should be used only after having been fitted for it by a doctor." On the later questionnaire, 81 percent knew that a diaphragm should be used along with a spermicidal cream or jelly, while 88 percent knew that it should be fitted by a doctor.

Only three statements dealt with the condom and, as with the prescription methods, misinformation was the rule for the initial questionnaire; but great improvement was shown on all three questions following the rap session. The smallest proportion of correct answers both times was to the (incorrect) statement, "Rubbers break easily," with only 18 percent replying correctly the first time and 31 percent the second. The authors commented, "This type of incorrect belief can needlessly curtail the use of con-

doms by teenagers and it may have contributed to the decision of these young women to begin using the pill."

On five questions dealing with other nonprescription contraceptives (spermicidal foams and jellies), correct answers ranged from 17 percent to 73 percent on the first questionnaire, and from 63 percent to 95 percent on the second survey. The one item which elicited the fewest correct responses both times (17 percent and 63 percent, respectively) was, "They [spermicides] should be washed out with a douche immediately after intercourse." Such a false notion could lead to totally ineffective usage.

In a miscellaneous section, eight questions explored knowledge of such items as rhythm, withdrawal and the menstrual cycle. On the first test, the smallest proportion of correct responses, 45 percent, was to the statement, "Sperm can live in the female's reproductive system for about 72 hours (three days)." The greatest proportion correct, 79 percent, was to the question, "A girl can get pregnant the first time she has intercourse." On the second test, 73 percent knew the correct answer to the first statement, while 87 percent answered the second correctly.

There was less of an increase in knowledge in two other areas—VD (six questions) and abortion (three questions)—but the original level of correct answers was relatively high for both these subjects (between 68 percent and 94 percent on VD, increasing to between 79 percent and 94 percent, and between 83 percent and 89 percent on abortion, increasing to between 89 percent and 93 percent).

Overall, the teenagers gave at least 28 correct answers to the 39 questions on the second survey, up from 18. Most of this increase was in the 30 questions on birth control, to which each girl gave an average of 12 correct answers on the first questionnaire and 21 on the second. The number of correct responses tended to increase with the age of the girls, with their grade in school and with their socioeconomic status. In addition, whites scored higher than other racial groups.

Knowledge increased for all groups, however. In fact, in all demographic breakdowns (by age, education, race or socioeconomic status), the group that scored lowest on the second test did better than the group that scored highest on the first test. "The implication of these results," observed the authors, "is that although the education session is providing a good deal of information, it can be made even more effective by directing special attention to the subgroups that score low on the prerap measure in order to bring them up to the same high postrap level attained by the subgroups that score high on the prerap test."

In addition to increasing the contraceptive knowledge of the teens participating in the rap sessions, the program has two other benefits, Reichelt and Werley pointed out: "because teenagers' major source of sex information is their peer group . . . it is important to get correct information to as large a part of the teen population as possible. And . . . the education sessions provide the teens with an opportunity to freely discuss their concerns in the psychosexual area."

Source

P. A. Reichelt and H. H. Werley, "Evaluation of Information Imparted in a Sexual-Contraceptive Educational Program for Teenagers," paper presented at the annual meeting of the American Psychological Association, New Orleans, Sept. 2, 1974.

Surveying Two Schools

High School Students Have Premarital Sex; Only 1 in 10 Parents Provides Sex Ed

A clear majority of middle- and lower-class high school students surveyed in two San Francisco area public high schools approves of premarital sex and the provision of contraception to teenagers without parental consent; well over half of those surveyed had actually had premarital sex, most of them without using contraception, and, despite the differences in the educational status of their parents, only about one out of 10 said their parents had been the source of their sexual knowledge. On the question of abortion, however, lower-class students were much less approving than middle-class students. These were some of the findings reported by Dr. Warren B. Miller, Director of the Laboratory of Behavior and Population at the Stanford University School of Medicine, who also noted that only about one-third of the respondents knew correctly when the fertile period occurred during the menstrual cycle, despite sex education classes in the middle-class high school.

Survey questionnaires were completed in class by 180 students (97 males, 83 females) in the middle-class school and 154 students (66 males, 88 females) in the lower-class school. All these students had obtained parental consent for their participation, as required by California law. The average age was the same (17.6 years), and almost all the students had never been married. In the middle-class school, almost all the students were white, while the lower-class school was racially mixed (65 Chicanos, 51 whites, 20 blacks, five Orientals and 13 other or unknown). In both schools similar proportions of the students said they were Protestants, but almost twice as many in the lower-class school said they were Catholics.

Similar proportions of students from the two schools reported having had sexual intercourse—53 percent of the males and 58 percent of the females at the middle-class school, and 64 percent of the males and 48 percent of the females at the lower-class school. The frequency of intercourse was also similar—about half of all groups reported having had intercourse only once or a "few times."

Attitudes about acceptability of sexual intercourse differed mainly according to the sex of the respondent. While about eight in 10 males from the middle-class school and seven in 10 from the lower-class school said sexual intercourse was acceptable for a man or woman if he or she were engaged, such action was approved by two-thirds of the middle-class females and half of the lower-class females. More than four in 10 males from both schools said sexual intercourse "with a good friend" was acceptable, but only half as many females approved.

Attitudes toward unmarried cohabitation showed the same pattern—approved by nearly three-fourths of the males but only half of the females. Approval of contraception for minors without parental consent was more widespread, endorsed by three-fourths of the males and two-thirds of the females in both schools. In regard to abortion, however, religion appeared to be the crucial variable: abortion was approved by two-thirds of the students from the middle-class school, but by only one-third of those from the lower-class school, which had a significantly higher proportion of Catholics.

Socioeconomic status made the difference on sources of sexual information. While only slightly more than one in 10 students from both schools said their parents were their "most complete source of sexual information," friends were the major source of information at the lower-class school (59 percent of the males, 50 percent of the females, compared with 32 percent of the males and 28 percent of the females at the middle-class school). About 40 percent of students at the middle-class school said school was the most common source of sex information, compared with eight percent of the males and 16 percent of the females at the lower-class school. A major factor in this difference was that "the lower-class school had no sex education program, while the middle-class school had a comprehensive program, one which was well received and popular among the students," Dr. Miller noted. Fear of pregnancy was a major deterrent to sexual intercourse at both schools but was more of a deterrent among middle-class girls, with 70 percent of them citing fear of pregnancy as a deterrent compared with 42 percent of the lower-class girls.

More students from the lower-class school reported having been involved in a pregnancy—20 percent of sexually active males and females, compared with 12.5 percent of sexually active females and two percent of males at the middle-class school. The difference reported by the middle-class males "quite likely . . . results from their not being informed by the girl when a pregnancy has occurred."

The outcomes of the pregnancies differed between schools: six of the nine pregnancies reported by middle-class students ended in legal abortion, two in miscarriage, and one was carried to term and given up for adoption. In the lower-class school, five of the 17 pregnancies ended in abortion (three legal and two illegal), four in miscarriage, five were carried to term (and the babies kept by the unwed mother), and in three cases the parents got married. These results, and the differing views on abortion, "support the general conclusion that ways of coping with unplanned pregnancies vary considerably by sex and social class."

Preferred Method

The pill was the preferred method of contraception among middle-class males and all females but a significantly smaller percentage of lower-class males preferred it. The IUD ranked second among all girls, with the condom preferred by equal proportions of males. Significantly more lower-class students chose the rhythm method, but this difference probably was due to the higher proportion of Catholics at the lower-class school, Dr. Miller noted. A significant proportion of lower-class males—17 percent—indicated their preferred method was one of the less effective methods such as withdrawal or foam.

Despite the preference of the middle-class students, both male and female, and the lower-class females for more effective methods, "most of the sexually active respondents had used either no contraception or a poor method (such as withdrawal or rhythm) on some occasion in the past." (Exact data on contraceptive use was not available.) This exposure to the risk of unwanted pregnancy was compounded by poor knowledge of when in the menstrual cycle the fertile period occurred. Only one-third of all males and lower-class females knew the answer. Middle-class females did somewhat better, with 43 percent of those not sexually active and 77 percent of those sexually active giving the correct response.

Overall, the students wanted to have an average of 2.24 children, but this varied by sex and school, from 2.06 for middle-class males and 2.23 for middle-class females, to 2.33 for lower-class males and 2.64 for lower-class females. About one-fourth of the lower-class students wanted four or more children, compared with fewer than 10 percent of the middle-class students.

Source

W. B. Miller, "Sexuality, Contraception and Pregnancy in a High School Population," *California Medicine*, **119**:14, 1973.

Oral Contraceptives

Researchers Doubt Vit. A Harms Babies

Investigators at Leeds University in England, although confirming "a significant increase in vitamin A levels in women taking oral contraceptives . . . , have been unable to show that either taking oral contraceptives shortly before pregnancy or a high vitamin A level during the first trimester of pregnancy, comparable to that of a woman taking oral contraceptives, has any detrimental effect on the outcome of pregnancy." The study, reported in the *British Medical Journal*, was prompted by previous reports that women using oral contraceptives have higher blood levels of vitamin A than women not taking the pill [see: "New Findings: Liver, Libido, Breasts, Vit. A," *Digest*, Vol. 1, No. 2, 1972, p. 14] and by research which indicated that high levels of vitamin A increase the chances of malformed offspring in experimental animals and might do the same in humans.

The researchers, Jennifer Wild, C. J. Schorah and Dr. R. W. Smithells, studied vitamin A levels of 534 women in the early stages of pregnancy—195 of them former pill users and 339 never-users. All the women were originally examined during the first 15 weeks of their pregnancies, with blood samples taken to determine vitamin A levels. Twenty-eight women had stopped pill use less than four months before giving blood samples; 63 women had last taken orals four to six months previously; 47 women had stopped pill use seven to 12 months previously; and 57 women had last used the pill more than a year before. The investigators found that there was "no significant difference in vitamin A levels in the first trimester of pregnancy between women who discontinued oral contraception shortly before conceiving and women who had never taken oral contraceptives," and no difference between these levels and those recorded in nonusers several months postpartum.

The researchers also reported on the proportion of abnormalities among the infants born to the various groups of women. Among those who had discontinued pill use less than 20 weeks before conception, there were 91 pregnancies: Four women miscarried, and three of the live-born infants had minor abnormalities, "which is no more than random expectation," they wrote. Among the women with the highest levels of vitamin A (greater than 94 mcg per 100 ml of blood serum), there were four spontaneous abortions among 55 pregnancies, and four minor congenital abnormalities, "which is again no more than random expectation." The outcome of one pregnancy was unknown. The investigators did confirm previous reports of higher vitamin A levels in users compared with nonusers when they examined 62 women at the time they brought their babies in for examination between six and 10 months postpartum. The 28 women who had resumed oral contraceptive use had a mean serum vitamin A level of 94 mcg per 100 ml, compared with 70 mcg per 100 ml for those not using orals.

One of the earlier researchers into the relationship between the pill, vitamin A and pregnancy disagreed with the findings of the Leeds investigators. In a letter to the *British Medical Journal*, Dr. Isabel Gal noted that the observations regarding women with the highest vitamin A levels may "not be altogether reassuring," since three of the four abnormalities seen were urogenital abnormalities of male infants—a high proportion when there were only 50 live births, both male and female, to this group of women. This "relatively high incidence . . . deserves attention because an influence of maternal progestogen therapy (from oral contraceptives) cannot be ruled out." The investigators' conclusions, she said, "may yet be more definite than is warranted by their data and should not be accepted as final. Further work is required."

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J. Wild, C. J. Schorah and R. W. Smithells, "Vitamin A, Pregnancy, and Oral Contraceptives," *British Medical Journal*, **1**:57, 1974.

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Oral Contraceptives

Pill Used by Estimated 50 Million Women, Mainly in Developed Countries and China

An estimated 50 million women around the world are currently using the pill, according to an analysis of pill distribution by P. T. Piotrow and Calvin M. Lee in *Population Report*. About 20 million regular users buy their supplies through pharmacies; organized government and private family planning programs provide the pill to an additional eight million users; and samples and donations provide pills for another two to three million women. In addition, between 13 million and 20 million women in mainland China are estimated to be regular pill users. In 1973, distribution through organized family planning programs nearly doubled, while commercial sales increased about 10 percent. By 1973, the authors note, "the only major areas of the world in which oral contraceptives were not readily available through health services or family planning programs were India, Japan, the USSR, and parts of Eastern Europe."

As of the first half of 1973, the countries with the highest percentages of women aged 15-44 purchasing oral contraceptives through commercial channels were The Netherlands (37 percent), New Zealand (31 percent), West Germany and Australia (each with 28 percent). About 20 percent of women who purchased the pill through commercial channels were in Austria, Belgium and the United States, but the U.S. figure does not include women who received oral contraceptives through organized family planning programs. The largest proportion of women aged 15-44 who purchased the pill commercially in developing countries were found in Argentina (seven percent) and Brazil (six percent).

In developing countries, however, noncommercial distribution of oral contraceptives through family planning programs helps make the pill available to many women who otherwise could not afford it. "The largest single source of oral contraceptives today for family planning programs in developing countries," Piotrow and Lee points out, "is the U.S. Agency for International Development" (AID). Between 1967 and 1973, AID sent an estimated 93 million cycles to 65 countries, with 120 million cycles projected for 1974 alone. Other major sources of pills for developing areas are the Swedish International Development Authority and UNICEF. "During 1973, donations [to Asia, Africa and Latin America] probably exceeded commercial sales," the authors observed.

Retail prices of the pill range from about $2.50 per cycle in the United States to $0.50-$1.00 in several developing countries. "Per capita income is a major factor influencing sales," the authors note, and in many areas of the world "even 50 cents is a substantial sum."

There has been a continuing "trend toward formulations containing lower doses of both estrogens and progestogens . . . ," the authors note, both because research showed that the smaller quantities provide effective contraception, and because several studies link estrogen dosage with increased risk of thromboembolism. By 1972, more than half (51 percent) of all combined pills contained only 50 mcg of estrogen, while 31 percent had 100 mcg or more. Progestogen content also declined, from all pills having 5 mg or 10 mg in 1963 to 77 percent having only 1.0 mg or 0.5 mg in 1972. Since 1972, progestogen-only 'minipills' and low-estrogen combined pills (with only 20 mcg or 30 mcg of estrogen) have been added to the armamentarium. Use of sequential preparations has declined because they have proven to be less effective than the combined pills and to carry a somewhat greater medical risk. "Used rarely in developing countries," the authors said, "[they] now supply only seven percent of the U.S. market, down from 22 percent in 1967."

Among developed countries, Ireland and Japan have approved oral contraceptives exclusively for therapeutic purposes—not for contraception (although studies have estimated that 7.2 percent of women aged 15-44 in Ireland and 0.8 percent in Japan do use the pill). The pill has also been difficult to obtain (although not prohibited for contraception) in India, the Soviet Union and parts of Eastern Europe. In mainland China, however, the pill is popular, with from 20-25 percent of women in need of family planning services in rural areas to two-thirds of such women in Peking using the pill, according to one report, Piotrow and Lee note. The package insert accompanying pills manufactured in Shanghai states that "the oral contraceptive is so far the best birth control method." The Chinese have also been responsible for some innovations in oral contraception, introducing low-dose pills in 1969 (four years before they were available in the United States and England) and currently experimenting with "sheet-type" pills —with the hormones impregnated in a water-soluble paper.

Source

P. T. Piotrow and C. M. Lee, "Oral Contraceptives—50 Million Users," *Population Report*, Series A, No. 1, April 1974.

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